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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/903,412

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Shohei Koide

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21186

7590

12/31/2002

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EXAMINER

WESSENDORF, TERESA D

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 12/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/903,412

Applicant(s)

KOIDE, SHOHEI

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) 1-50 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8, drawn to a fibronectin type III molecule with mutation.
- II. Claims 9, 13-17 drawn to a fibronectin type III polypeptide monobody comprising of a plurality of Fn3  $\beta$ -strand.
- III. Claims 10-12, drawn to a nucleic acid, vector and host cell.
- IV. Claims 18-21, drawn to a nucleic acid, vector and host cell expressing the polypeptide of claim 1.
- V. Claim 22, drawn to a method of preparing FN3 polypeptide monobody.
- VI. Claim 23, drawn to a method of preparing a Fn3 polypeptide monobody comprising the step of preparing a PCR primer.
- VII. Claim 24, drawn to a method of preparing a polypeptide monobody comprising site-directed mutagenesis.
- VIII. Claim 25, drawn to a kit.

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- IX. Claims 26-37, drawn to a variegated nucleic acid library.
- X. Claims 38-40, drawn to a peptide display library.
- XI. Claim 41, drawn to a method of identifying the amino acid sequence of a polypeptide that forms a complex.
- XII. Claim 42, drawn to a method of preparing a variegated nucleic acid library.
- XIII. Claim 43, drawn to a method of identifying an amino acid sequence of a polypeptide capable of catalyzing a chemical reaction.
- XIV. Claim 44, drawn to a method of preparing a variegated nucleic acid library with mutations.
- XV. Claim 45, drawn to an isolated polypeptide.
- XVI. Claim 46, drawn to an isolated polypeptide.
- XVII. Claims 47 and 49, drawn to a kit and polypeptide.
- XVIII. Claims 48 and 50, drawn to a kit and polypeptide.

The inventions are distinct, each from the other because of the following reasons:

Inventions (I, II) and (III, IV) are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are

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patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product(nucleic acid) is deemed to be useful as probe and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Inventions V-VII and XI-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different methods of preparing different products and identifying for a product, each processes utilizing different steps and/or starting material and have different effects.

Inventions (I, II) and (V, VI, VII) are related as process of making and product made. The inventions are distinct if

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either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different processes as in the different claimed processes of groups V-VII or by using library by in vitro method.

Inventions I, II, III, IV, VIII, IX, X, XV, XVI, XVII and XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to structurally different compounds with different functions or effects and can be prepared by different methods. For example, nucleic acid of Group III can be used as a probe; the polypeptide of Groups XV and XVI can be obtained from a screening a display library. Therefore, the polypeptide of Groups I and II would have different structures from the polypeptides isolated from a phage display library of Groups XV and XVI. The kit comprises additional components besides the main polypeptide component e.g., instructions for using said kit.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and the search required for Group I is not required for Group II-XVIII, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

If Group I is elected, elect a single species as follows:

A. Asp mutation:

1. Deletion, specify the positions (only one position)
2. Substitution, specify the specific residue (one residue at one position of the peptide sequence, for example either Asn or Lys as recited in claim 4).

If Group II is elected:

A. In the loop region: (for only one residue)

1. Deletion
2. Insertion
3. Replacement

B. Property of a). binding to form a complex or b). catalyzing a reaction.

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C. Loop regions comprises from one of the following sequences:

(i)-(vi).

If Group IX is elected:

A. elect the peptide sequence in the loop regions from (i)-(v) as recited in claim 27 or claims 32-36.

B. Deletion or replacement or insertion

C. Stop or cys codon as recited in claim 31.

Each of the species recited in each of the subgroups is distinct in structure, possibly resulting in different effects. A prior art reference anticipating one species would not render obvious the other species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1, 9, 18, 25 and 26 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are



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generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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**REASSIGNMENT OF LOCATION**

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit **1639**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

T.D.   
T. D. Wessendorf  
Primary Examiner  
Art Unit 1639

tdw

December 30, 2002